UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,605	02/12/2007	Albert B. Deisseroth	036222-0212	7449

82622 7590 07/07/2010

Esther E. Min
13 Oak Treat Ct.
Walnut Creek, CA 94597

EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
07/07/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,605	DEISSEROTH ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *13-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/04/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I with traverse in Response to Election Requirement, filed 03/30/2010, is acknowledged.

The traversal is on the grounds that the prior art of Curiel et al. and McCown et al. each teach a technology distinct from that of applicant and neither anticipates the adenoviral expression product claim set forth in claim 1.

With respect to Curiel et al. (U.S. Patent No. 6,284,742) (892; of record),
applicant argues that Curiel et al. does not use secretion in the sense of applicant's invention, that the CD40L is not internal to the vector and manipulates dendritic cells and B cells,
while applicant's infected cells release the tumor antigen CD40L fusion proteins, which is then free to bind to the dendritic ells to activate them and to antigen load them unlike the Curiel et al. patent.

With respect to McCown et al. (U.S. patent No. 7,071,172) (892; of record),
applicant argues that McCown et al. does not disclose employment of a viral vector carrying a transcription unit which encompassed a polypeptide line to the CD40 ligand from which the transmembrane domains have been removed and attaching it to an antigen in order to make the target antigen more immunogenic, which would not let CD40L be released from the infected cells,
while applicant's vector attaching CD40L to a target antigen to make the target antigen more immunogenic and employs only the extracellular domain of the CD40L.

In addition, applicant argues that McCown et al. is directed towards an adenovirus-associated virus and not an adenovirus as claimed by applicant.

Last but not least, applicant relies upon the category of specifying a product of use of said product for Unity of Invention.

Given applicant's remarks, the prior art rejection herein will address applicant's arguments as to the distinguishing features of the claimed invention in the interest of compact prosecution.

However, applicant is reminded that the claims are given their broadest reasonable interpretation and differences in the nature of secretion may not limiting.

Also, the lack of unity of invention may be found in terms of both anticipation and obviousness.

Applicant is reminded that rejoinder practice is available for the instant application such that if the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

Claims 1-12 are under consideration in the instant application as the elected invention.

Claims 13-34 have been withdrawn from prosecution as being drawn to a non-elected invention.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

3. Applicant should amend page 1 of the specification to indicate the priority documents relied upon in the instant application.

4. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected. Appropriate corrections are required.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

5. Claims 10-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-11 are indefinite in reciting "residues 1-23 and 47-261" of CD40 ligand because the referenced sequence(s) (SEQ ID NO(S)) is (are) not recited.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

6. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. §§ 102(f) or (g) prior art under 35 U.S.C. § 103(a).

7. Claims 1-2 and 4-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Curiel et al. (U.S. Patent No. 6,284,742) (892; of record) in view of Xiang (J. Immunol. 167: 4560-4565, 2001) (1449; #A91), Zheng et al. (Cancer Research 61: 8127-8134m 2001) (1449; #A96) Hu et al. (PNAS 96: 8161-8166, 1999), Dreyfus et al. (US 2002/0068048) and Thomas (US 2005/0048645).

Curiel et al. teach recombinant adenoviral vectors, comprising CD40L and a tumor or infectious agent antigen to manipulate the immune response for a person in need having a disease such as cancer or an infectious disease (e.g., see entire document, including Summary of the Invention and Detailed Description of the Invention, including columns 10-11).

Curiel et al. differs from the claimed invention by not explicitly describing all of the claimed properties of the claimed adenoviral expression vector, including that the CD40 ligand is missing all or substantially all of the transmembrane domain rendering he CD40L secretable.

While Xiang et al. teach a Salmonella typhimurium vector rather than an adenoviral vector, Xiang et al. teach a dual-function DNA vaccine encoding a tumor antigen and CD40 ligand trimer (see entire document, including Abstract, Results and Discussion).

While Zheng et al. teach the use of fusion proteins, Zheng et al. teach the use of the extracellular domain of CD40L for the induction of antitumor immunity (see entire document, including Abstract, Materials and Methods, Results and Discussion)

In addition to the teachings of Xiang et al. and Zheng et al.,
Thomas et al. teach the soluble CD40L, including the extracellular domain region of CD40L or fusion proteins comprising the extracelluar domain of CD40L is sufficient for stimulating immune responses of interest (See entire document, including paragraphs [0035], [0037]-[0049]).

While Hu et al. does not teach the use of CD40L as an immunotherapy treatment for cancer with targeting,
Hu et al. teach the use of the same or nearly the same adenoviral vectors for delivery of cancer modulators of interest (see entire document, including Abstract, Adenoviral Vectors in Materials and Methods and Discussion).
In addition to the teachings of Hu et al.,
Dreyfus et al. teach the advantages of viral vectors such as adenovirus for efficient delivery of nucleic sequences coding for a secretable therapeutic peptides (see entire document, including paragraphs [0097], [0124], [0140] and Claim 11).

Given the teachings herein, it would have been obvious to one of ordinary skill in the art to make and use adenoviral expression vectors comprising CD40L, including the extracellular domain of CD40L with a tumor antigen to stimulate antitumor responses to tumors of interest. By employing the extracellular domain of CD40L, the expression vectors would not have the transmembrane or cytoplasmic regions of CD40L and would also provide for the secretion or soluble nature of CD40L. Human cytomegalovirus promoter/enhancer were known and obvious regulators of transcription in expression vectors of interest at the time the invention was made. The prior art teaches the advantages of stimulatory properties of CD40L to stimulate immune responses, including in therapeutic regimens of treating tumors. The prior art teaches the advantages of adenoviral vectors in delivery of modulators of tumor immunity. From the teachings of the references, a person of ordinary skill in the art would have a reasonable expectation of success at the time the invention was made. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Curiel et al. (U.S. Patent No. 6,284,742) (892; of record) in view of Xiang et al. (J. Immunol. 167: 4560-4565, 2001) (1449; #A91), Zheng et al. (Cancer Research 61: 8127-8134, 2001) (1449; #A96) Hu et al. (PNAS 96: 8161-8166, 1999), Dreyfus et al. (US 2002/0068048) and Thomas (US 2005/0048645) as applied to claims 1-2 and 4-12 above and further in view of Lamikanra et al. (J. Virol. 75: 9654-9664, 2001) (1449: #A63).

The teachings of Curiel et al., Xiang et al., Hu et al., Dreyfus et al., Thomas are set forth above and differ by not explicitly teaching E7 of human papilloma virus as a targeted tumor antigen.

Lamikanra et al. teach targeting E7 of human papilloma virus as a target antigen of treating tumors of interest (see entire document).

Given the teachings herein, it would have been obvious to one of ordinary skill in the art to substitute E7 of human papilloma virus as the tumor antigen of interest in the making and using adenoviral expression vectors comprising CD40L, including the extracellular domain of CD40L with a tumor antigen to stimulate antitumor responses to tumors of interest as taught above. From the teachings of the references, a person of ordinary skill in the art would have a reasonable expectation of success at the time the invention was made. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. Given the number of copending applications by the inventorship, applicant is invited to clarify which applications should be subject to rejections under the judicially created doctrine of obviousness-type double patenting.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/

Primary Examiner
Technology Center 1600
Art Unit 1644
July 6, 2010